DEPARTM

Centers for Medicare & Medicaid Services

[Document Identifiers: CMS-10668 and CMS-10455]

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Centers for Medicare & Medicaid Services, Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: The Centers for Medicare & Medicaid Services (CMS) is announcing an opportunity for the public to comment on CMS' intention to collect information from the public. Under the Paperwork Reduction Act of 1995 (the PRA), federal agencies are required to publish notice in the *Federal Register* concerning each proposed collection of information (including each proposed extension or reinstatement of an existing collection of information) and to allow 60 days for public comment on the proposed action. Interested persons are invited to send comments regarding our burden estimates or any other aspect of this collection of information, including the necessity and utility of the proposed information collection for the proper performance of the agency's functions, the accuracy of the estimated burden, ways to enhance the quality, utility, and clarity of the information to be collected, and the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

DATES: Comments must be received by **[INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]**.

ADDRESSES: When commenting, please reference the document identifier or OMB control number. To be assured consideration, comments and recommendations must be submitted in any one of the following ways:

1. *Electronically.* You may send your comments electronically to http://www.regulations.gov. Follow the instructions for "Comment or Submission" or "More Search Options" to find the information collection document(s) that are accepting comments.

2. *By regular mail.* You may mail written comments to the following address:

CMS, Office of Strategic Operations and Regulatory Affairs

Division of Regulations Development

Attention: Document Identifier/OMB Control Number: _____

Room C4-26-05

7500 Security Boulevard

Baltimore, Maryland 21244-1850.

To obtain copies of a supporting statement and any related forms for the proposed collection(s) summarized in this notice, you may make your request using one of following:

1. Access CMS' Web Site address at Web Site address at https://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing

FOR FURTHER INFORMATION CONTACT: William N. Parham at (410) 786-4669.

SUPPLEMENTARY INFORMATION:

Contents

This notice sets out a summary of the use and burden associated with the following information collections. More detailed information can be found in each collection's supporting statement and associated materials (see **ADDRESSES**).

CMS-10668 Applications for Part C Medicare Advantage, 1876 Cost Plans, and Employer Group Waiver Plans to Provide Part C Benefits

CMS-10455 Report of a Hospital Death Associated with Restraint or Seclusion

Under the PRA (44 U.S.C. 3501-3520), federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. The term "collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA

requires federal agencies to publish a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, CMS is publishing this notice.

Information Collection

1. *Type of Information Collection Request:* Revision of a currently approved collection; Quality Measures and Administrative Procedures for the Hospital-Acquired Condition Reduction Program; *Use*: The Centers for Medicare & Medicaid Services (CMS) is committed to promoting higher quality healthcare and improving outcomes for Medicare beneficiaries. The Hospital-Acquired Condition (HAC) Reduction Program is established by section 1886(p) of the Social Security Act, as added by Section 3008 of the Affordable Care Act (Pub. L. 111-148), and requires the Secretary to reduce payments to subsection (d) hospitals in the worst-performing quartile of all subsection (d) hospitals by 1 percent effective beginning on October 1, 2014 and subsequent years. For the FY 2025 program year we are proposing in the Fiscal Year (FY) 2023 Inpatient Prospective Payment System (IPPS)/Long-Term Care Hospital (LTCH) PPS proposed rule to suppress all six measures in the HAC Reduction Program and not calculate measure scores or Total HAC Scores for any hospital such that no hospital will receive a payment reduction due to the significant impacts of the COVID-19 pandemic on the quality measures. We are not proposing any policies in the FY 2023 IPPS/LTCH PPS proposed rule which result in a change to our estimated burden. To administer its requirements, the HAC Reduction Program relies on data collection established through the Centers for Disease Control and Prevention's (CDC) OMB control number, 0920-0666, and validation processes established through the Hospital Inpatient Quality Reporting (IQR) Program's OMB control number, 0938-1022. However, in the FY 2019 IPPS/LTCH PPS final rule, the Hospital IQR Program finalized the removal of the CDC National Healthcare Safety Network (NHSN) Healthcare-associated Infection (HAI) measures and NHSN HAI validation processes beginning on January 1, 2020.

To continue validation of these measures, the HAC Reduction Program adopted validation templates similar to the ones previously used under the Hospital IQR Program. These templates continue the HAC Reduction Program's use and validation of NHSN HAI data.

The HAC Reduction Program identifies the worst-performing quartile of hospitals by calculating a Total HAC Score derived from the CMS Patient Safety and Adverse Events Composite (CMS PSI 90) and NHSN HAI measures, which require that we collect claims-based and chart-abstracted measures data, respectively. The HAC Reduction Program validates NHSN HAI data reported by subsection (d) hospitals to ensure that hospitals report correct NHSH HAI measure data, and the Total HAC Score is calculated using accurate data. The HAC Reduction Program may penalize any hospitals that fail validation by assigning the maximum Winsorized z-score for the set of measures that fail validation, for use in the Total HAC Score calculation. The collection of information for validation is necessary to ensure that the HAC Reduction Program and Total HAC Score are administered fairly.

The HAC Reduction Program will continue to receive NHSN HAI data for hospitals from CDC. Because the burden associated with submitting data for the HAI measures (CDI, CAUTI, CLABSI, MRSA, and SSI) is captured under a separate OMB control number, 0920-0666, we do not provide an independent estimate of the burden associated with collecting data for these measures for the HAC Reduction Program. We also do not provide an estimate of burden for the claims-based PSI 90 measure, because this measure is collected using Medicare FFS claims that hospitals are already submitting to the Medicare program for payment purposes. We also do not provide an estimate of burden for validation of data submitted for the PSI 90 measure, because Medicare claims are audited under the Medicare Fee for Service (FFS) Recovery Audit Program. *Form Number*: CMS-10668 (OMB control number: 0938-1352); *Frequency*: Yearly; *Affected Public*: Private Sector (Business or other for-profit and Not-for-profit institutions) Federal Government, and State, Local or Tribal Governments; *Number of Respondents*: 400; *Total*

Annual Responses: 400; *Total Annual Hours*: 28,800. (For policy questions regarding this collection contact Jennifer Tate at 410-786-0428).

2. *Type of Information Collection Request*: Revision of a currently approved collection; *Title of Information Collection*: Report of a Hospital Death Associated with Restraint or Seclusion; *Use*: Provisions implementing this statutory reporting requirement for hospitals participating in Medicare are found at 42 CFR 482.13(g), as revised in the final rule that published on May 16, 2012 (77 FR 29034). This regulation also applies to Critical Access Hospitals (CAHs) with distinct part units (DPUs); since CAH DPUs are subject to the Hospital Conditions of Participation. The regulation at 42 CFR 482.13(g) requires that hospitals and CAHs with DPUs report deaths associated with the use of restraint and/or seclusion directly to the CMS locations. This regulation requires that information about patient deaths associated with the use of restraint and/or seclusion must be reported to the CMS Locations using the online CMS-10455 form titled "*Report Of A Hospital Death Associated With The Use Of Restraint Or Seclusion."*

When a death occurs in a hospital (including Critical Access Hospital (CAH) with a rehabilitation or psychiatric Distinct Part Unit (DPU)) that is associated with the use of restraints and/or seclusion, the hospital staff must complete the online Form CMS-10455 (42 CFR 482.13(g)(1). The hospital staff must also document the date and time that CMS was notified of the death in the patient's medical record (42 CFR 482.13(g)(3)(i).

When a death occurs during the use of 2-point soft cloth wrist restraints with no seclusion, or within 24 hours after the patient was removed from such restraints, the hospital must document the information required by 42 CFR 482.13(g)(4)(ii) into a hospital log or internal system within 7 days from the date of death (42 CFR 482.13(g)(4)(i). The hospital is not required to submit this log or internal records to the CMS Location, however, they must be made available in either written or electronic form to CMS immediately upon request (42 CFR 482.13(g)(4)(iii). In addition, the hospital staff must also document the date and time that the

required information was entered into the hospital's log or internal system in the patient's medical record (42 CFR 482.13(g)(3)(ii). *Form Number*: CMS-10455 (OMB control number: 0938-1210); *Frequency*: Occasionally; *Affected Public*: Private Sector; *Number of Respondents*: 3,137; *Number of Responses*: 3,137; *Total Annual Hours*: 1,210. (For policy questions regarding this collection contact Caroline Gallaher at 410-786-8705.)

Dated: June 8, 2022.

William N. Parham, III,

Director,

Paperwork Reduction Staff,

Office of Strategic Operations and Regulatory Affairs.

4120-01-U-P

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